Objection to Drawings

The drawings are objected to as being informal.

Formal drawings are being provided herewith for review.

Specification

It has been requested that the specification be reviewed for any errors.

Applicant is not aware of any pending errors, and in fact corrected errors as noted in the Preliminary Amendment filed with the Specification on October 19, 2002.

Rejection of Claim 1 and 17-32 under 35 U.S.C. § 112, Second Paragraph

Claim 1 is rejected under 35 U.S.C. § 112, second paragraph as being indefinite.

Claim 1 has been canceled thereby obviating the basis for this rejection.

Applicant respectfully requests reconsideration and withdrawal of this rejection.

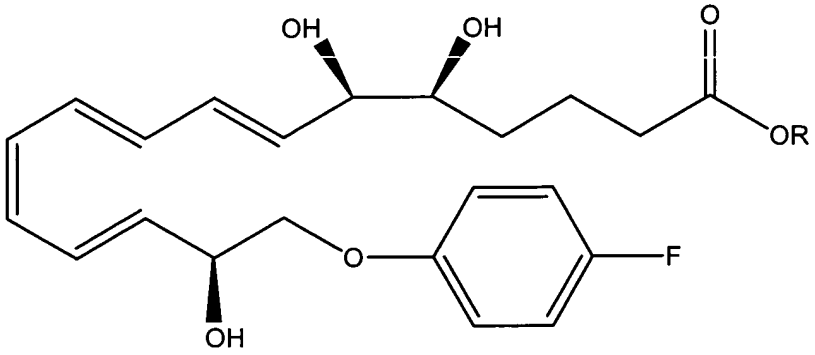
Rejection of Claims 1 and 17 through 32 under 35 U.S.C. § 103(a)

Claims 1 and 17 through 32 are rejected under 35 U.S.C. §103(a) as being unpatentable over "Biochemistry and Cell Biology of Phospholipase D in Human Neutrophils", Chemistry and Physics of Lipids, 80, 3 (1996) (hereinafter "Olson") in view of "Neutrophil-mediated Changes in Vascular Permeability Are Inhibited by Topical Application of Aspirin-triggered 15-epi-lipoxin A_4 and Novel Lipoxin B_4 Stable Analogues" J. Clin. Invest. 101, 819 (1998) (hereinafter "Takano").

Claim 1 has been canceled, thereby obviating this basis for rejection.

The present invention is directed to methods for the modulation of a disease or condition associated with phospholipase D (PLD) initiated polymorphoneutrophil (PMN) inflammation; methods for treatment of PLD initiated polymorphoneutrophil (PMN) inflammation; methods for

the modulation of a disease or condition associated with PLD initiated superoxide generation or degranulation activity; methods for treatment of PLD initiated superoxide generation or degranulation activity in a subject by the administration of an effective anti-inflammatory amount of a lipoxin analog to the subject. The lipoxin analog has the formula



Additionally, the present invention also relates to packaged pharmaceutical compositions which contain the lipoxin analog and instructions to treat the afflictions described above.

Olson describes a ***biochemical pathway*** for receptor-activated phospholipase -D (PLD) in isolated neutrophils and inflammation. ***Olson fails to teach any subject matter regarding any treatment associated with such above identified afflictions***.

Olson, the primary reference, fails to teach or suggest, provide any motivation or an expectation of success so that one of ordinary skill in the art would utilize ***any of the lipoxin analogs***, described throughout the application, as pharmaceuticals capable of modulating a disease or condition associated with phospholipase D (PLD) initiated polymorphoneutrophil (PMN) inflammation or for treatment of PLD initiated polymorphoneutrophil (PMN) inflammation or for the modulation of a disease or condition associated with PLD initiated superoxide generation or degranulation activity or for treatment of PLD initiated superoxide generation or degranulation activity.

Olson also fails to teach or suggest, provide any motivation or an expectation of success so that one of ordinary skill in the art would utilize ***any of the lipoxin analogs***, described

throughout the application, in ***packaged pharmaceuticals*** with instructions for the treatment of a disease or condition associated with phospholipase D (PLD) initiated polymorphoneutrophil (PMN) inflammation or for treatment of PLD initiated polymorphoneutrophil (PMN) inflammation or for the modulation of a disease or condition associated with PLD initiated superoxide generation or degranulation activity or for treatment of PLD initiated superoxide generation or degranulation activity inflammation in a subject.

Takano, the secondary reference, fails to remedy the deficiencies of Olson. Takano teaches leukotriene B_4 (LTB_4)-induced vascular permeability change and PMN infiltration caused by the application of LTB_4 to a mouse ear. Takano fails to teach or suggest PLD-initiated PMN inflammation, let alone a method for modulating or treating a disease or condition associated with PLD initiated PMN inflammation.

Takano fails to teach or suggest, provide any motivation or an expectation of success so that one of ordinary skill in the art would utilize ***any of the lipoxin analogs***, described throughout the application, as pharmaceuticals capable of modulating a disease or condition associated with phospholipase D (PLD) initiated polymorphoneutrophil (PMN) inflammation or for treatment of PLD initiated polymorphoneutrophil (PMN) inflammation or for the modulation of a disease or condition associated with PLD initiated superoxide generation or degranulation activity or for treatment of PLD initiated superoxide generation or degranulation activityin a subject.

Takano also fails to teach or suggest, provide any motivation or an expectation of success so that one of ordinary skill in the art would utilize ***any of the lipoxin analogs***, described throughout the application, in ***packaged pharmaceuticals*** with instructions for treatment of a disease or condition associated with phospholipase D (PLD) initiated polymorphoneutrophil (PMN) inflammation or for treatment of PLD initiated polymorphoneutrophil (PMN) inflammation or for the modulation of a disease or condition associated with PLD initiated superoxide generation or degranulation activity or for treatment of PLD initiated superoxide generation or degranulation activityin a subject.

Neither reference, alone or in combination teaches or suggests, provides any motivation or an expectation of success so that one of ordinary skill in the art would utilize ***any of the lipoxin analogs***, described throughout the application, as pharmaceuticals capable of modulating a disease or condition associated with phospholipase D (PLD) initiated polymorphoneutrophil (PMN) inflammation or for treatment of PLD initiated polymorphoneutrophil (PMN) inflammation or for the modulation of a disease or condition associated with PLD initiated superoxide generation or degranulation activity or for treatment of PLD initiated superoxide generation or degranulation activityinflammation in a subject.

Neither reference, alone or in combination, teaches or suggests, provides any motivation or an expectation of success so that one of ordinary skill in the art would utilize ***any of the lipoxin analogs***, described throughout the application, in ***packaged pharmaceuticals*** with instructions for modulating a disease or condition associated with phospholipase D (PLD) initiated polymorphoneutrophil (PMN) inflammation or for treatment of PLD initiated polymorphoneutrophil (PMN) inflammation or for the modulation of a disease or condition associated with PLD initiated superoxide generation or degranulation activity or for treatment of PLD initiated superoxide generation or degranulation activityin a subject.

Therefore, claims 17-32 are in allowable form. Reconsideration and withdrawal of the pending rejection is respectfully requested.

Double Patenting

Claim 1 is rejected under 35 U.S.C. § 101 as claiming the same invention as that of claim 1 of prior U.S. Patent No. 6,387,953.

Claim 1 has been canceled, thereby obviating the basis for this rejection.

Obviousness-type Double Patenting

Claims 17-32 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-24 of U.S. Patent No. 6,387,953.

Upon Notice of Allowance, Applicant is willing to provide a terminal disclaimer with regard to U.S. Patent No. 6,387,953, thereby obviating the basis for this rejection.

Claims 1 and 17-32 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 5,441,951 (hereinafter '951). Applicant respectfully traverses the basis of this rejection.

U.S. Patent '951 does not teach or suggest, provide any motivation or an expectation of success so that one of ordinary skill in the art would utilize ***the lipoxin analogs***, described throughout the application, as pharmaceuticals capable of modulating a disease or condition associated with ***phospholipase D (PLD) initiated polymorphoneutrophil (PMN) inflammation*** or for treatment of ***PLD initiated polymorphoneutrophil (PMN) inflammation*** or for the modulation of a disease or condition associated with ***PLD initiated superoxide generation or degranulation activity*** or for treatment of ***PLD initiated superoxide generation or degranulation*** activity in a subject.

Furthermore, the '951 patent does not teach or suggest, provide any motivation or an expectation of success so that one of ordinary skill in the art would utilize ***the lipoxin analogs***, described throughout the application, in ***packaged pharmaceuticals*** with instructions for modulating a disease or condition associated with ***phospholipase D (PLD) initiated polymorphoneutrophil (PMN) inflammation*** or for treatment of ***PLD initiated polymorphoneutrophil (PMN) inflammation*** or for the modulation of a disease or condition associated with ***PLD initiated superoxide generation or degranulation activity*** or for treatment of ***PLD initiated superoxide generation or degranulation activity*** in a subject.

Therefore, claims 17-32 are in allowable form. Reconsideration and withdrawal of the pending rejection is respectfully requested.

Conclusion

In view of the foregoing, Applicant submits that all pending claims distinguish over all references cited by the Examiner and respectfully requests that all rejections be withdrawn. The Examiner is invited to telephone the undersigned attorney for Applicant in the event that such communication is deemed to expedite prosecution of this application.

Respectfully submitted,

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By: _____

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